

JUL 17 1998

**510(k) SUMMARY**  
**Dornier Surgical Products, Inc.'s**  
**MediLas H Pulsed Laser**

**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

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**Contact Person:**

Carol Wernecke  
Director of Regulatory and Clinical Affairs  
1155 Roberts Boulevard  
Kennesaw, GA 30144

Date Prepared: May 14, 1998

**Name of Device and Name/Address of Sponsor**

Medilas H Pulsed Holmium YAG Laser

Dornier Medical Systems, Inc.  
1155 Roberts Boulevard  
Kennesaw, GA 30144

**Classification Name**

HO: YAG lasers have not been specifically classified by FDA.

**Predicate Devices**

Dornier Medilas Fibertome Laser Model 5100 and Coherent's VersaPulse 2.1.

## **Intended Use**

The Dornier Medilas H Laser is intended to be used in cutting, vaporization, ablation, and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, and colonoscopes), or in incision/excision, vaporization, ablation and coagulation of soft tissue in contact or non-contact open surgery. The Dornier Medilas H Laser is indicated for use in medicine and surgery, in the following specialities: Urology, Pulmonology, Arthroscopy, Lithotripsy, Gastroenterology, Gynecology, ENT, and General Surgery.

## **Technological Characteristics and Substantial Equivalence**

The Dornier Medilas H Pulsed Holmium YAG Laser is a compact pulsed HO:Yag laser emitting laser radiation in the invisible range of 2080 nm. The Medilas H provides a temperature controlled method for contact cutting and non contact coagulation and vaporization with a bare fiber.

The Medilas H has the same principles of operation and similar technological characteristics as previously cleared predicates, the Dornier Medilas fibertome 5100 and Coherent's VersaPulse 2.1.

The Medilas H and the 5100 laser have photoelectric power meters and both are automatically calibrated. Both laser have a 2-stage, waterproof and explosion-proof, foot switch and both laser incorporate a watchdog monitored microprocessor.

There are minor differences between the Medilas H and its predicate, none of which present new issues of safety or effectiveness. The Medilas H and the 5100 offers adjustable pulse durations, or continuous. The maximum power of both aiming beam at the aperture is 1 mW.

Both the Medilas H and the 5100 laser incorporates a graphic display panel. The Medilas H graphic display shows laser operating parameters, application modes, time functions, system status and messages for the user.

Whereas, its predicate devices offers several modes of operation to include the standard, the Medilas H offer only a software controlled Standard operating mode. The Standard mode is used for non-contact coagulation and vaporization.

Like the 5100 laser, the Medilas H has a cooling system which includes an air-cooled, temperature controlled internal closed circuit water system. The cooling system in the Medilas H is identical to the system included in the previously cleared 510(k) for the Medilas 5100 (K964760). In order to conduct away the

heat produced by the laser pump lamp, the cooling circuit dissipates a maximum of approximately 1.5 kW of heat. This permits a maximum of approximately 15 minutes of uninterrupted operation at full laser power before the maximum permissible water temperature of 77o F (25oC) is reached.

As a safety feature, the Medilas H and the 5100 has a single rotating magnetic shutter which moves the filter out of the laser beam. One microprocessor controls the shutters. The Medilas H and the 5100 laser is based on a single shutter with two parallel running microprocessors. Whenever one microprocessor runs differently from the other, the Medilas H laser hardware initiated a "system fault" routine. During any "system fault" laser production and release immediately halt.

### **Performance Data**

While no performance standard have been established for HO: YAG lasers under Section 514 of the Federal Food, Drug and Cosmetic Act, the Dornier Medilas H laser is in compliance with class IV performance standards for light emitting products promulgated under the Radiation Control Health and Safety Act of 1968. See 21 C.F.R. § 1040.10 and §1040.11. the laser also complies with the applicable requirements of the following voluntary standards: IEC-601, IEC 825/VDE 0837/2.86.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Dornier Surgical Products, Inc.  
c/o Ms. Carol Wernecke  
Director of Regulatory and Clinical Affairs  
Dornier Medical Systems, Inc.  
1155 Robert Boulevard  
Kennesaw, Georgia 30144

Re: K981718  
Trade Name: Dornier Medilas H Laser System  
Regulatory Class: II  
Product Code: GEX  
Dated: May 14, 1998  
Received: May 15, 1998

Dear Ms. Wernecke:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

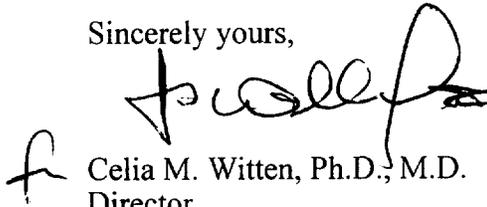
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "C. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

